

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Alston et al.	Group Art Unit: 3771
Application No: 10/714,511 Confirmation No: 9835	Examiner: Dixon, Annette Fredricka
Filed: November 14, 2003	Attorney Docket No: 53305-US-CNT (NV.0175.00)
Title: AEROSOLIZATION APPARATUS WITH NON-CIRCULAR AEROSOLIZATION CHAMBER	March 1, 2010 San Francisco, California

**SUPPLEMENTAL APPEAL BRIEF**

**VIA ELECTRONIC FILING**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Examiner:

In response to the Examiner's Final Rejection of August 10, 2009 and the Notice of Appeal filed on November 10, 2009, the Applicant of the above-referenced patent application (hereinafter Appellant) hereby appeals to the Board of Patent Appeals and Interferences. Appellant requests the reversal of the Final Rejection. This Appeal Brief is supplemental to the Appeal Brief of January 11, 2010 and is responsive to the Notice of Non-Compliant Appeal Brief of January 27, 2010.

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By:

  
Melanie Hitchcock

Date: March 1, 2010

**(1) *Real Party in Interest***

The real party in interest of the present application is Novartis AG (by way of assignment from Novartis Pharmaceuticals AG and from Nektar Therapeutics, which was formerly Inhale Therapeutic Systems, Inc.), having a place of business at Forum 1, Novartis Campus, CH-4056 Basel, Switzerland.

**(2) *Related Appeals and Interferences***

Appellant, Appellant's legal representative, and assignee are aware of no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

**(3) *Status of Claims***

Claims 1-9, 11-20, 22-24 and 26-47 are presently pending in the case. Claims 1-9, 11-20, 22-24 and 26-47 have been finally rejected. The rejection of each of claims 1-9, 11-20, 22-24 and 26-47 is hereby appealed.

Claims 10, 21 and 25 have been cancelled.

**(4) *Status of Amendments***

No amendments have been filed after Final Office Action. Accordingly, all amendments submitted during prosecution have been entered.

**(5) Summary of the Claimed Subject Matter**

As recited in claim 1, described on pages 6-11, and shown in Figures 1-4, an aerosolization apparatus (100) comprises a body (105) defining a chamber (110) having an air inlet (115) and an air outlet (120), wherein the chamber (110) is sized to receive a receptacle (125) containing a pharmaceutical formulation in a manner which allows the receptacle (125) to move within the chamber (see page 7 lines 10-22). The air inlet (115) is oriented to cause air to swirl within the chamber (see Figures 2A and 2B). The chamber (110) comprises a longitudinal axis which is substantially parallel to an inhalation direction (see page 8 lines 26-30) and the chamber (110) has a sidewall with a cross-section orthogonal to the longitudinal axis that is non-circular (see element 170 in Figures 2A, 2B and 3A-3H). The receptacle (125) contacts the non-circular cross-section (170) of the sidewall when the receptacle moves within the chamber (110, and see page 7 line 24 through page 8 line 7). When a user inhales, air enters into the chamber through the inlet (115) to cause the receptacle (125) to move within the chamber (110) so that the receptacle (125) is disturbed by the contact with the non-circular cross-section (170) of the sidewall and the pharmaceutical formulation exits through an opening in the receptacle and is aerosolized for delivery to the user through the outlet (120).

As recited in claim 15, described on pages 6-11, and shown in Figures 1-4, an aerosolization apparatus (100) comprises a body (105) defining a chamber (110) having an air inlet (115) and an air outlet (120), wherein the chamber (110) is sized to receive a receptacle (125) containing a pharmaceutical formulation in a manner which allows the receptacle (125) to move within the chamber (see page 7 lines 10-22). The air inlet (115) is oriented to cause air to swirl within the chamber (see Figures 2A and 2B). The chamber (110) comprises a longitudinal axis which is substantially parallel to an axis (160) passing centrally through the outlet (120), and the chamber (110) has a sidewall with a cross-section orthogonal to the longitudinal axis that is non-circular (see element

170 in Figures 2A, 2B and 3A-3H. The receptacle (125) contacts the non-circular cross-section (170) of the sidewall when the receptacle moves within the chamber (110, and see page 7 line 24 through page 8 line 7). When a user inhales, air enters into the chamber through the inlet (115) to cause the receptacle (125) to move within the chamber (110) so that the receptacle (125) is disturbed by the contact with the non-circular cross-section (170) of the sidewall and the pharmaceutical formulation exits through an opening in the receptacle and is aerosolized for delivery to the user through the outlet (120).

As recited in claim 22, described on pages 6-11, and shown in Figures 1-4, an aerosolization apparatus (100) comprises a body (105) defining a chamber (110) having an air inlet (115) and an air outlet (120), wherein the chamber (110) is sized to receive a receptacle (125) containing a pharmaceutical formulation in a manner which allows the receptacle (125) to move within the chamber (see page 7 lines 10-22). The air inlet (115) is oriented to cause air to swirl within the chamber (see Figures 2A and 2B). The chamber (110) comprises a longitudinal axis which is substantially perpendicular to an inhalation direction (see page 4 lines 18-26) and the chamber (110) has a sidewall with a cross-section orthogonal to the longitudinal axis that is non-circular (see element 170 in Figures 2A, 2B and 3A-3H). The receptacle (125) contacts the non-circular cross-section (170) of the sidewall when the receptacle moves within the chamber (110, and see page 7 line 24 through page 8 line 7). When a user inhales, air enters into the chamber through the inlet (115) to cause the receptacle (125) to move within the chamber (110) so that the receptacle (125) is disturbed by the contact with the non-circular cross-section (170) of the sidewall and the pharmaceutical formulation exits through an opening in the receptacle and is aerosolized for delivery to the user through the outlet (120).

As recited in claim 26, described on pages 6-11, and shown in Figures 1-4, a method of aerosolizing a pharmaceutical formulation comprises providing a receptacle (125) containing a pharmaceutical formulation. The receptacle (125) is inserted into a

chamber (110) having a non-circular cross section (170). A user inhales through an opening (120) in the housing to cause air to flow into the chamber (110), thereby causing the receptacle (125) to move (see page 7 lines 10-22) about the non-circular cross section (see element 170 in Figures 2A, 2B, and 3A-3H) to aerosolize the pharmaceutical formulation.

#### **(6) *Grounds of Rejection to be Reviewed on Appeal***

Appellant requests review of the Examiner's following grounds of rejection:

Claims 1-9, 11-20, 22-24 and 26-47 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,705,313 to Niccolai (hereinafter Niccolai) in view of U.S. Patent 2,946,332 to Sacks (hereinafter Sacks).

#### **(7) *Argument***

Appellant believes each of claims 1-9, 11-20, 22-24 and 26-47 are improperly rejected and are therefore allowable for the following reasons.

The Examiner's rejection of claims 1-9, 11-20, 22-24 and 26-40 under 35 USC §103(a) as being unpatentable over Niccolai in view of Sacks is improper and should be reversed.

The rejection of independent claim 1 under §103(a) is improper

Niccolai and Sacks do not render independent claim 1 unpatentable. Claim 1 is to an aerosolization apparatus comprising, *inter alia*, a chamber having a sidewall with a cross-section that is non-circular wherein a receptacle contacts the non-circular cross-section of the sidewall when the receptacle moves within the chamber, whereby when a

user inhales, air enters into the chamber to cause the receptacle to move within the chamber so that the receptacle is disturbed by the contact with the non-circular cross-section of the sidewall. Niccolai and Sacks do not disclose or teach this aerosolization mechanism as recited in claim 1 in a manner that would render claim 1 unpatentable under 35 U.S.C. §103(a), as will be explained.

Niccolai alone does not disclose a chamber with a non-circular cross section that is contacted by a receptacle. Instead, in the Niccolai device, a receptacle 18 contacts a circular cross-section of the chamber (see Figure 2). Niccolai's chamber does have non-circular portions (*e.g.*, where the openings 20 are provided). However, these non-circular portions are not contacted by the capsule of Niccolai during the aerosolization process. As can be seen in Figure 2 of Niccolai, during aerosolization the Niccolai capsule contacts the forward wall (9) and the other end of the capsule slides or rotates about a **circular** section of the chamber just forward of the openings (20). This operation is much like that of Appellant's claimed device in claim 1, except for the fact that Appellant's capsule rotates or slides about a **non-circular** section of the sidewall. Niccolai lacks this non-circular feature. Accordingly, Niccolai alone fails to render claim 1 unpatentable.

The teachings of Sacks do not make up for the deficiencies of Niccolai. Sacks discloses ribs (30) on which a capsule (12) is seated (see column 2 lines 17-20) and a shank (32) which firmly engages the capsule onto the ribs (see column 3 lines 18-22). In Sacks, the capsule does not move in the chamber and the disclosed ribs are not contacted by a moving capsule during aerosolization. Therefore, Sacks does not disclose an aerosolization mechanism or chamber arrangement as claimed by Appellant in claim 1.

Since neither Niccolai nor Sacks discloses the chamber arrangement claimed by Appellant in claim 1, the Examiner has failed to establish a *prima facie* case under 35 U.S.C. §103(a). In other words, Niccolai fails to disclose the claimed aerosolization mechanism (*i.e.*, a moving receptacle that contacts a non-circular sidewall), and even if

one of ordinary skill in the art were to replace the aerosolization mechanism of Sacks with the one of Niccolai, the resulting device would still not have an aerosolization mechanism as recited in claim 1. More specifically, if the Niccolai device were to be modified by adding ribs (30) and shank (32) as taught by Sacks, the capsule within the Niccolai device would be firmly seated thereon and would not move during a user's inhalation. Thus, several positively recited claim limitations in claim 1 would not be met. For example, claim 1 recites, "wherein the chamber is sized to receive a receptacle containing a pharmaceutical formulation in a manner which allows the receptacle to move within the chamber"; "wherein the receptacle contacts the non-circular cross-section of the sidewall when the receptacle moves within the chamber"; and "whereby when a user inhales, air enters into the chamber through the inlet to cause the receptacle to move within the chamber so that the receptacle is disturbed by the contact with the non-circular cross-section of the sidewall." A device as modified by the Examiner's proposal would not meet at least these limitations.

Furthermore, the Examiner's proposed modification would not have been obvious to one having ordinary skill in the art because make such modification would go against the teachings of Niccolai and would render the Niccolai device inoperative. The aerosolization of the medicament in the capsule of Niccolai is achieved by lifting, rotation, and shaking of the capsule caused by the airflow through the chamber (see column 3 lines 40-58). With the Examiner's proposed modification, the capsule would be seated and not able to move, and thus, not able to be lifted, rotated, and shaken. Thus, there would be little or no aerosolization achieved. Furthermore, the Sacks aerosolization mechanism is based on the entrainment of medicament as air flows into the capsule and out the other end of the capsule whereas Niccolai only punctures one end of the capsule. Therefore, if the capsule is seated in Niccolai, there is nowhere for the aerosolized medicament to flow.

Finally, one of ordinary skill in the art would not have found it obvious to merely take the ribs of Sacks and place them on the side walls of the chamber of Niccolai, as the Examiner appears to be contending to be obvious, because one of ordinary skill in

the art would have had no reason or motivation to do so. The aerosolization mechanisms of Niccolai and Sacks are not similar. There would be no reason for one of ordinary skill in the art to take ribs taught for use in securing a capsule and place them onto a sidewall portion that is not at all involved in securing a capsule. Following this line of reasoning, and by way of making Appellant's point by analogy, it would be "obvious" to place parking lot speed bumps on a race course. Clearly, such willy-nilly placement of parts is not within the purview of 35 U.S.C. §103(a). Instead, the Examiner has used impermissible hindsight reasoning in constructing a case of obviousness entirely absent any motivation other than that taught by Appellant.

For at least these reasons, Niccolai and Sacks do not render independent claim 1 unpatentable. Accordingly, reversal of rejection of claim 1 under 35 U.S.C. §103(a) is requested.

The rejection of independent claim 15 under §103(a) is also improper

Niccolai and Sacks also do not render independent claim 15 unpatentable. Claim 15 is to an aerosolization apparatus comprising, *inter alia*, a chamber sized to receive a receptacle containing a pharmaceutical formulation in a manner which allows the receptacle to move within the chamber, wherein the chamber has a sidewall with a cross-section that is non-circular and wherein the receptacle contacts the non-circular cross-section of the sidewall when the receptacle moves within the chamber, whereby when a user inhales, air enters into the chamber to cause the receptacle to move within the chamber so that the receptacle is disturbed by the contact with the non-circular cross-section of the sidewall. As discussed above, Niccolai does not disclose a non-circular sidewall that is contacted by a receptacle. As also discussed above, Sacks does not make up for the deficiencies of Niccolai. Accordingly, claim 15 is not properly rejected under 35 U.S.C. §103(a), and Appellant requests reversal of the rejection.



The rejection of independent claim 22 under §103(a) is also improper

Niccolai and Sacks also do not render independent claim 22 unpatentable. Claim 22 is to an aerosolization apparatus comprising, *inter alia*, a chamber sized to receive a receptacle containing a pharmaceutical formulation in a manner which allows the receptacle to move within the chamber wherein the chamber has a sidewall with a cross-section that is non-circular and wherein the receptacle contacts the non-circular cross-section of the sidewall when the receptacle moves within the chamber, whereby when a user inhales, air enters into the chamber to cause the receptacle to move within the chamber so that the receptacle is disturbed by the contact with the non-circular cross-section. As discussed above, Niccolai does not disclose a non-circular sidewall that is contacted by a receptacle. As also discussed above, Sacks does not make up for the deficiencies of Niccolai. Accordingly, claim 22 is not properly rejected under 35 U.S.C. §103(a), and Appellant requests reversal of the rejection.

The rejection of independent claim 26 under §103(a) is also improper

Niccolai and Sacks also do not render independent claim 26 unpatentable. Claim 26 is to a method of aerosolizing a pharmaceutical formulation, the method comprising, *inter alia*, inserting a receptacle into a chamber having a non-circular cross section and causing the receptacle to move about the non-circular cross section to aerosolize the pharmaceutical formulation. Niccolai does not disclose a receptacle that moves about a non-circular cross section to aerosolize a pharmaceutical formulation. Sacks does not make up for the deficiencies of Niccolai, as discussed above. Accordingly, claim 26 is not properly rejected under 35 U.S.C. §103(a), and Appellant requests reversal of the rejection.

The dependent claims are also improperly rejected

Claims 2-9 and 11-14 are also not rendered unpatentable by Niccolai and Sacks. Claims 2-9 and 11-14 depend from claim 1 and are not rendered unpatentable by Niccolai and Sacks for at least the same reasons as the claim from which they depend. Reversal of the rejections under 35 USC §103(a) is requested.

Claims 16-20 and 29-32 are also not rendered unpatentable by Niccolai and Sacks. Claims 16-20 and 29-32 depend from claim 15 and are not rendered unpatentable by Niccolai and Sacks for at least the same reasons as the claim from which they depend. Reversal of the rejections under 35 USC §103(a) is requested.

Claims 23, 24 and 33-36 are also not rendered unpatentable by Niccolai and Sacks. Claims 23, 24 and 33-36 depend from claim 22 and are not rendered unpatentable by Niccolai and Sacks for at least the same reasons as the claim from which they depend. Reversal of the rejections under 35 USC §103(a) is requested.

Claims 27, 28 and 37-40 are also not rendered unpatentable by Niccolai and Sacks. Claims 27, 28 and 37-40 depend from claim 26 and are not rendered unpatentable by Niccolai and Sacks for at least the same reasons as the claim from which they depend. Reversal of the rejections under 35 USC §103(a) is requested.

## Conclusion

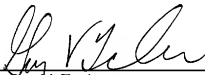
Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

JANAH & ASSOCIATES

Dated: March 1, 2010

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## **(8) Claims Appendix**

1. An aerosolization apparatus comprising:  
a body defining a chamber having an air inlet and an air outlet, wherein the chamber is sized to receive a receptacle containing a pharmaceutical formulation in a manner which allows the receptacle to move within the chamber and wherein the air inlet is oriented to cause air to swirl within the chamber;  
wherein the chamber comprises a longitudinal axis which is substantially parallel to an inhalation direction and wherein the chamber has a sidewall with a cross-section orthogonal to the longitudinal axis of the chamber that is non-circular and wherein the receptacle contacts the non-circular cross-section of the sidewall when the receptacle moves within the chamber,  
whereby when a user inhales, air enters into the chamber through the inlet to cause the receptacle to move within the chamber so that the receptacle is disturbed by the contact with the non-circular cross-section of the sidewall and the pharmaceutical formulation exits through an opening in the receptacle and is aerosolized for delivery to the user through the outlet.
2. An apparatus according to claim 1 wherein the receptacle is a capsule.
3. An according to claim 2 wherein the longitudinal axis of the chamber and the longitudinal axis of the capsule form an angle of less than about 45 degrees during use.
4. An apparatus according to claim 2 wherein the chamber is elongated and wherein the capsule is received lengthwise within the elongated chamber.
5. An apparatus according to claim 2 wherein the width of the chamber is less than the length of the capsule.

6. An apparatus according to claim 1 further comprising a puncturing member moveable within the chamber to create the opening in the receptacle.
7. An apparatus according to claim 6 wherein the puncture member comprises a sharpened tip for penetrating the wall of the receptacle.
8. An apparatus according to claim 6 wherein the puncture member comprises a pair of sharpened tips for penetrating the wall of the receptacle.
9. An apparatus according to claim 6 wherein the puncture member is positioned to pierce only one end of the receptacle.
11. An apparatus according to claim 1 wherein the non-circular cross-section comprises one or more projections that extend into the chamber.
12. An apparatus according to claim 1 wherein the non-circular cross-section comprises one or more indentations that extend inwardly into sidewalls of the chamber.
13. An apparatus according to claim 1 wherein the non-circular cross-section is a polygon.
14. An apparatus according to claim 1 wherein the non-circular cross-section is oval.

15. An aerosolization apparatus comprising:  
a body defining a chamber having an air inlet and an air outlet, wherein the chamber is sized to receive a receptacle containing a pharmaceutical formulation in a manner which allows the receptacle to move within the chamber and wherein the air inlet is oriented to cause air to swirl within the chamber;  
wherein the chamber comprises a longitudinal axis which is substantially parallel to an axis passing centrally through the outlet and wherein the chamber has a sidewall with a cross-section orthogonal to the longitudinal axis of the chamber that is non-circular and wherein the receptacle contacts the non-circular cross-section of the sidewall when the receptacle moves within the chamber,  
whereby when a user inhales, air enters into the chamber through the inlet to cause the receptacle to move within the chamber so that the receptacle is disturbed by the contact with the non-circular cross-section of the sidewall and the pharmaceutical formulation exits through an opening in the receptacle and is aerosolized for delivery to the user through the outlet.
16. An apparatus according to claim 15 wherein the receptacle is a capsule.
17. An according to claim 16 wherein the longitudinal axis of the chamber and the longitudinal axis of the capsule form an angle of less than about 45 degrees during use.
18. An apparatus according to claim 16 wherein the chamber is elongated and wherein the capsule is received lengthwise within the elongated chamber.
19. An apparatus according to claim 16 wherein the width of the chamber is less than the length of the capsule.
20. An apparatus according to claim 15 further comprising a puncturing member moveable within the chamber to create the opening in the receptacle.

22. An aerosolization apparatus comprising:
- a body defining a chamber having an air inlet and an air outlet, wherein the chamber is sized to receive a receptacle containing a pharmaceutical formulation in a manner which allows the receptacle to move within the chamber and wherein the air inlet is oriented to cause air to swirl within the chamber;
  - wherein the chamber comprises a longitudinal axis which is substantially perpendicular to an inhalation direction and wherein the chamber has a sidewall with a cross-section along a plane parallel to the longitudinal axis of the chamber, the cross-section being non-circular and wherein the receptacle contacts the non-circular cross-section of the sidewall when the receptacle moves within the chamber,
  - whereby when a user inhales, air enters into the chamber through the inlet to cause the receptacle to move within the chamber so that the receptacle is disturbed by the contact with the non-circular cross-section of the sidewall and the pharmaceutical formulation exits through an opening in the receptacle and is aerosolized for delivery to the user through the outlet.
23. An apparatus according to claim 22 wherein the receptacle is a capsule.
24. An apparatus according to claim 22 further comprising a puncturing member moveable within the chamber to create the opening in the receptacle.
26. A method of aerosolizing a pharmaceutical formulation, the method comprising:
- providing a receptacle containing a pharmaceutical formulation;
  - inserting the receptacle into a chamber having a non-circular cross section; and
  - inhaling through an opening in the housing to cause air to flow into the chamber thereby causing the receptacle to move about the non-circular cross section to aerosolize the pharmaceutical formulation.

27. A method according to claim 26 wherein the receptacle is a capsule.
28. A method according to claim 27 wherein the chamber is elongated and wherein the capsule is inserted lengthwise into the elongated chamber.
29. An apparatus according to claim 15 wherein the non-circular cross-section comprises one or more projections that extend into the chamber.
30. An apparatus according to claim 15 wherein the non-circular cross-section comprises one or more indentations that extend inwardly into sidewalls of the chamber.
31. An apparatus according to claim 15 wherein the non-circular cross-section is a polygon.
32. An apparatus according to claim 15 wherein the non-circular cross-section is oval.
33. An apparatus according to claim 22 wherein the non-circular cross-section comprises one or more projections that extend into the chamber.
34. An apparatus according to claim 22 wherein the non-circular cross-section comprises one or more indentations that extend inwardly into sidewalls of the chamber.
35. An apparatus according to claim 22 wherein the non-circular cross-section is a polygon.
36. An apparatus according to claim 22 wherein the non-circular cross-section is oval.
37. A method according to claim 26 wherein the non-circular cross-section comprises one or more projections that extend into the chamber.



38. A method according to claim 26 wherein the non-circular cross-section comprises one or more indentations that extend inwardly into sidewalls of the chamber.

39. A method according to claim 26 wherein the non-circular cross-section is a polygon.

40. A method according to claim 26 wherein the non-circular cross-section is oval.

41. An apparatus according to claim 20 wherein the puncture member comprises a pair of sharpened tips for penetrating the wall of the receptacle.

42. An apparatus according to claim 20 wherein the puncture member is positioned to pierce only one end of the receptacle.

43. An apparatus according to claim 24 wherein the puncture member comprises a pair of sharpened tips for penetrating the wall of the receptacle.

44. An apparatus according to claim 24 wherein the puncture member is positioned to pierce only one end of the receptacle.

45. A method according to claim 26 further comprising puncturing the receptacle to create an opening in the receptacle when the receptacle is in the chamber.

46. A method according to claim 45 wherein the step of puncturing comprises creating two openings in the receptacle.

47. A method according to claim 45 the step of puncturing comprises creating one or more openings on only one end of the receptacle.

**(9) Evidence Appendix**

none

**(10) Related Proceedings Appendix**

none